

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	Iwadata et al.	Art Unit:	Not Yet Assigned
Serial No.:	10/585,884	Examiner:	Not Yet Assigned
Filed:	July 12, 2006	Customer No.:	21559
Title:	GENE THERAPY FOR TUMORS USING MINUS-STRAND RNA VIRAL VECTORS ENCODING IMMUNOSTIMULATORY CYTOKINES (AS AMENDED)		

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

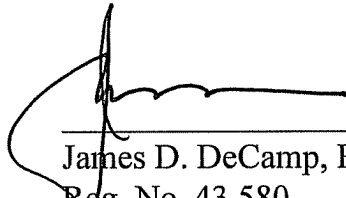
SUBMISSION OF TRANSLATION OF  
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

Applicants submit herewith the Translation of the International Preliminary Report on Patentability corresponding to the above-referenced application. Applicants petition for any necessary extensions of time for submission of this document.

In addition, if there are any charges, or any credits, please apply them to Deposit  
Account No. 03-2095.

Respectfully submitted,

Date: 26 December 2006



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From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

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JAPON



Date of mailing (day/month/year) 26 October 2006 (26.10.2006)	
Applicant's or agent's file reference D3-A0309P	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/JP2005/000238	International filing date (day/month/year) 12 January 2005 (12.01.2005)
Applicant DNAVEC RESEARCH INC. et al	

## 1. Transmittal of the translation to the applicant.

☐

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☒

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

EP, KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
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**TRANSLATION**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>D3-A0309P</b>	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. <b>PCT/JP2005/000238</b>	International filing date (day/month/year) <b>12.01.2005</b>	Priority date (day/month/year) <b>13.01.2004</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K48/00, A61K38/00, A61K35/12, A61K35/76, A61K39/00, A61P35/00, C12N5/10, C12N15/09</b>		
Applicant <b>DNAVEC RESEARCH INC.</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2005/000238

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_ as originally filed/furnished
- pages<sup>1</sup> \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages<sup>2</sup> \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- nos. \_\_\_\_\_ as originally filed/furnished
- nos.<sup>1</sup> \_\_\_\_\_ as amended (together with any statement) under Article 19
- nos.<sup>2</sup> \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- nos.<sup>3</sup> \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- sheets \_\_\_\_\_ as originally filed/furnished
- sheets<sup>1</sup> \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- sheets<sup>2</sup> \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-6

because:

☒ the said international application, or the said claims Nos. 1-6  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 1 to 6 pertain to methods for the  
treatment of the human body by means of surgery or  
therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-6

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2005/000238

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	7-10	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	7-10	NO
Industrial applicability (IA)	Claims	7-10	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
[Citations]			
Document 1: JP 07-503455 A (San Diego Regional Cancer Center), 13 April 1995			
Document 2: JP 58-157723 A (Ajinomoto Co., Inc.), 19 September 1983			
Document 3: Mol. Ther., 2003, Vol. 7, No. 2, pages 210 to 217			
Document 4: The Cell, 2001, Vol. 33, No. 6, pages 227 to 231			
[Explanations]			
<u>Claims 7 to 10</u>			
<p>The invention set forth in claims 7 to 10 is not disclosed in any of the documents that are cited in the international search report; therefore, said invention is novel. However, the invention in question does not involve an inventive step in the light of documents 1 to 4 cited in the international search report.</p> <p>Document 1 discloses anti-tumor agents that contain tumor antigens and cells that are capable of expressing a</p>			

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

cytokine gene product such as IL-2, while document 2 discloses anti-tumor agents that contain IL-2.

Meanwhile, gene therapy is a well-known technique for administering a protein as a medicament, and gene therapy techniques that employ a minus-strand RNA virus vector as a gene expression vector are also well known, as disclosed in documents 3 and 4. Such being the case, it would have been obvious to a person skilled in the art to apply a configuration that employs a minus-strand RNA virus vector in order to administer a cytokine such as the protein IL-2 in the anti-tumor agents that are disclosed in documents 1 and 2. Furthermore, it is common practice for a person skilled in the art to confirm whether cytokines such as IL-2 exhibit an anti-tumor effect against each type of tumor.



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing
    - ☒ contained in the international application as filed
    - ☐ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
    - ☐ received by this Authority as an amendment\* on \_\_\_\_\_
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."